



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Application of Advances in Nucleic Acid and Protein Based Detection Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Application of Advances in Nucleic Acid and Protein Based Detection Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations.” The purpose of this public workshop is to discuss research and development of multiplex assays and the use of these tests in blood donor screening and blood cell antigen typing. The public workshop has been planned in partnership with the AABB (formerly known as the American Association of Blood Banks), Advanced Medical Technology Association (AdvaMed), America’s Blood Centers, Department of Defense, Department of Health and Human Services Office of the Assistant Secretary for Health, and the National Heart, Lung and Blood Institute, National Institutes of Health. The public workshop will include presentations and panel discussions by experts from academic institutions, blood establishments, industry, and government agencies.

Date and Time: The public workshop will be held on April 10, 2013, from 8 a.m. to 5:30 p.m., and April 11, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held in the Main Auditorium, Natcher Conference Center, National Institutes of Health, Bldg. 45, Bethesda, MD 20892.

Contact Person: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6128, FAX: 301-827-2843, email: CBEROBRRWorkshops@fda.hhs.gov.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see Contact Person) by April 1, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Jennifer Scharpf (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The objectives of the workshop are to review the status of multiplex platforms and the technological advances in gene based and protein based pathogen and blood cell antigen detection methods and to discuss the scientific pathways to support the development of multiplex assays to screen blood donors for blood-borne pathogens and blood cell antigen typing.

The first day of this workshop will include presentations and panel discussions on the following topics: (1) Blood safety and infectious agents, (2) advances in blood-borne pathogen detection, and (3) molecular DNA-based typing of blood cell antigens.

The second day of the workshop will include presentations and discussion on the following topics: (1) Highly multiplexed technologies in blood donor screening; (2) bioinformatics, data

analysis, and data management issues; (3) perspectives in developing multiplex devices for donor screening; and (4) workshop summary and conclusions.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: March 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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